#### IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS Fort Worth Division

OUTSOURCING FACILITIES ASSOCIATION, et al.,

Plaintiffs,

v.

Civil Action No. 4:24-cv-00953-P

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

### Appendix (VOL IV of IV) in Support of Plaintiffs' Motion for a <u>Preliminary Injunction and Stay Pending Review</u>

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## **Certificate of Service**

I hereby certify that a true and accurate copy of the foregoing document was filed electronically (via CM/ECF) on January 28, 2025, and that I caused a copy of the foregoing, and all accompanying papers, to be served via process server and via U.S. mail on the following:

United States Food and Drug Administration 10903 New Hampshire Ave. Silver Spring, Maryland 20903 Dated: January 28, 2025

#### /s/ Ty Doyle

TY DOYLE (Texas Bar No. 24072075)
BAKER & HOSTETLER LLP
811 Main Street, Suite 1100
Houston, TX 77002
(713) 646-1374
tgdoyle@bakerlaw.com

Attorney for Plaintiffs

# Exhibit 39



Compounding the Joy of Living®

December 17, 2024

Robert Califf, MD Commissioner

Valerie Jensen Director, Drug Shortage Staff

Gail Bormel, JD
Director, Office of Compounding Quality and Compliance
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Subject: Formal Comment Regarding the Shortage of FDA-Approved Tirzepatide Injection Products

Dear Commissioner Califf, Ms. Jensen, and Dr. Bormel:

On behalf of the Alliance for Pharmacy Compounding, I am writing to express our continued concerns regarding the October removal of tirzepatide from the FDA's drug shortage list and the significant impact it will have on patient access. Since our previous correspondence, we have gathered updated monthly dispensing data from forty compounding pharmacies, representing only a fraction of compounders preparing these medications.

These forty pharmacies collectively dispensed **125,000 compounded tirzepatide prescriptions** over the past month, underscoring the critical role that compounded tirzepatide has played in addressing gaps in patient care during this shortage.

This data clearly demonstrates the ongoing unmet demand for FDA-approved tirzepatide, which compounded products are currently filling to support patient care. As the FDA works to stabilize the supply chain for FDA-approved medications, we urgently ask the agency to:

- 1. Reinstate tirzepatide on the FDA drug shortage list, which would allow 503A pharmacies and 503B outsourcing facilities to continue to compound copies of these medications, or
- 2. Permit compounded products to remain available under enforcement discretion until the FDA-approved supply is sufficient to meet patient needs, and
- 3. Ensure transparency in communications with the pharmacy community about anticipated timelines for resolving shortages.

We also request a dialogue to discuss the implications of the shortage list removal, as well as broader issues surrounding drug shortages. Recent screenshots from wholesalers, attached to this letter, indicate persistent limited availability of tirzepatide despite incremental improvements in the supply chain.

The data we have provided highlights a clear and urgent need for action to safeguard patient access to essential therapies. We ask the FDA to acknowledge these ongoing shortages and allow compounding to continue until such a time as FDA-approved products are fully available to meet demand.

Thank you for your attention to this matter. APC remains committed to collaborating with the agency to ensure patients receive uninterrupted access to essential medications.

Sincerely,

Tenille Davis, PharmD, RPh, BCSCP, FAPC

Chief Advocacy Officer

**Alliance for Pharmacy Compounding** 

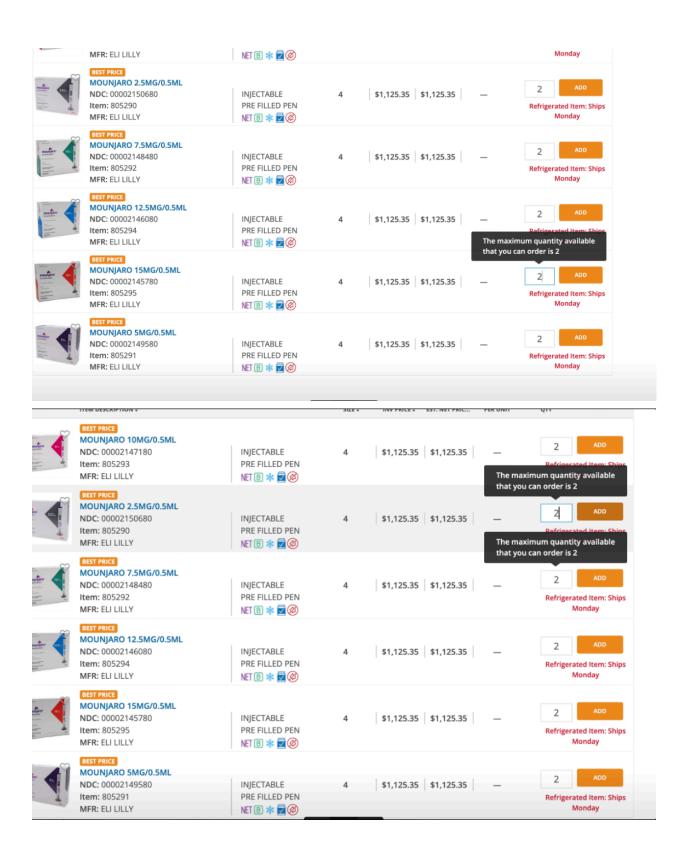
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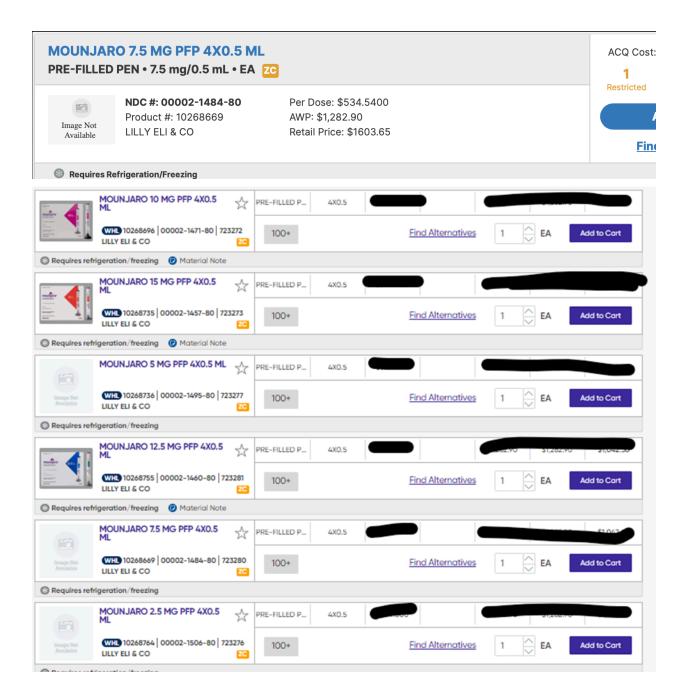
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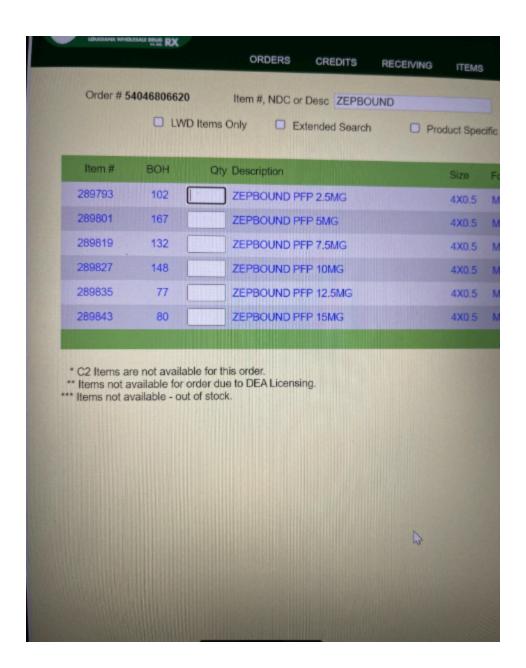
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Pharmacy C	0
Pharmacy D	3705
Pharmacy E	0
Pharmacy F	15000
Pharmacy G	3500
Pharmacy H	31000
Pharmacy I	6877
Pharmacy J	1200
Pharmacy K	70
Pharmacy L	3400
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Pharmacy R	2300
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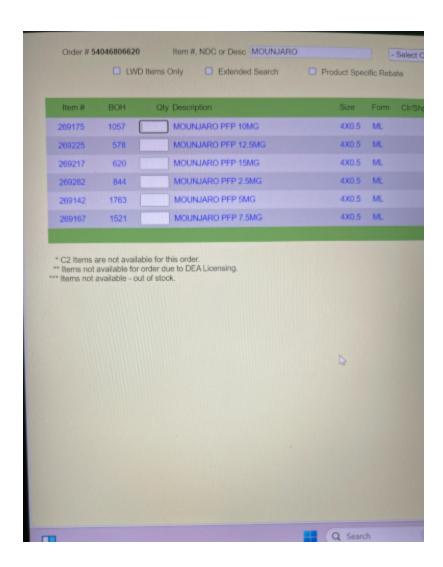
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Pharmacy W	4000
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Pharmacy AA	500
Pharmacy BB	391
Pharmacy CC	4000
Pharmacy DD	886
Pharmacy EE	4500
Pharmacy FF	5600
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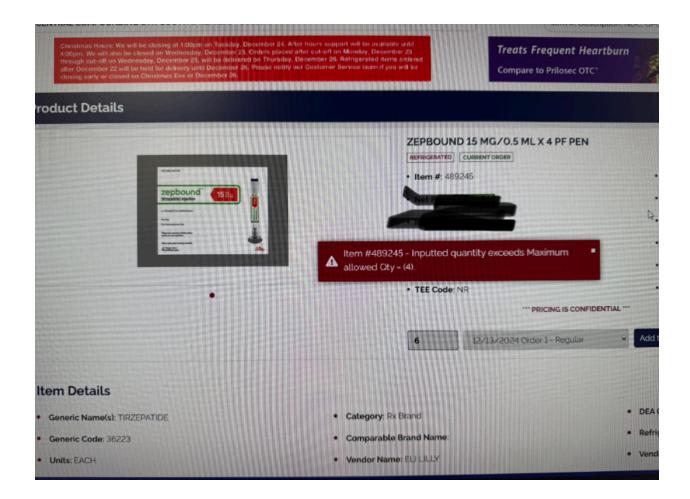
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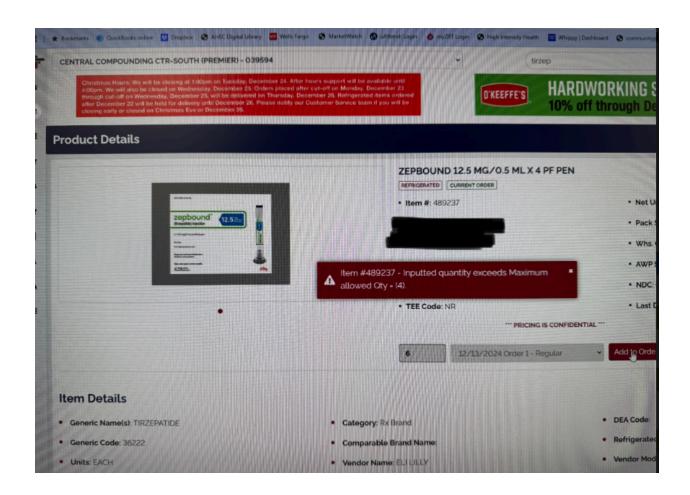


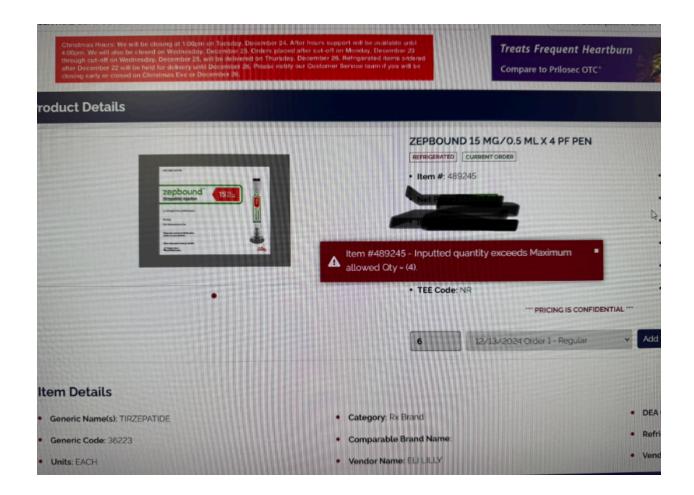


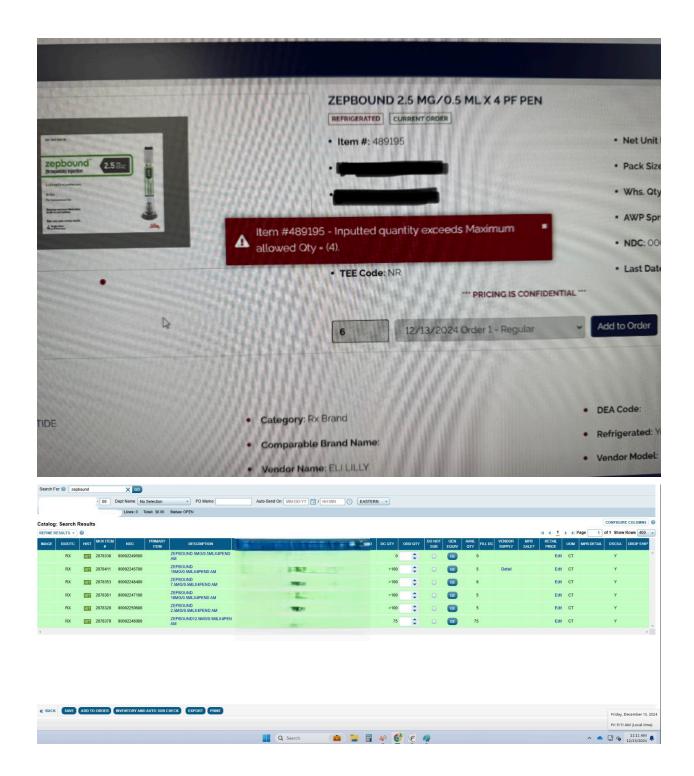


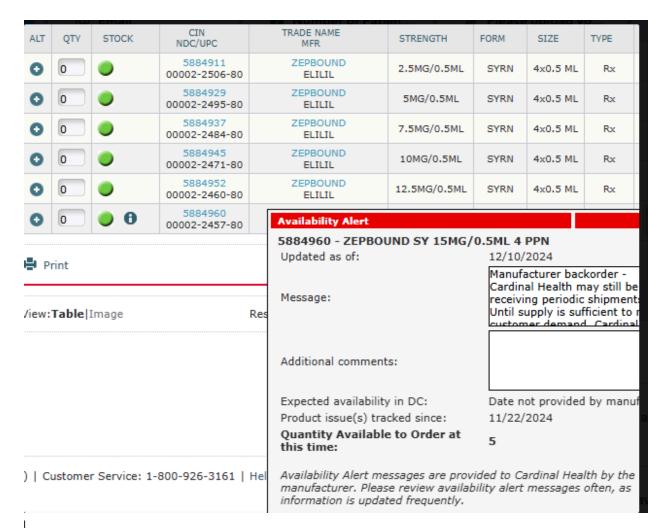












Generic Name: TIRZEPATIDE Description: ZEPBOUND SY

2.5MG/0.5ML 4 PPN

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NDC: 00002-2506-80 UPC: 300022-506802

Contract:

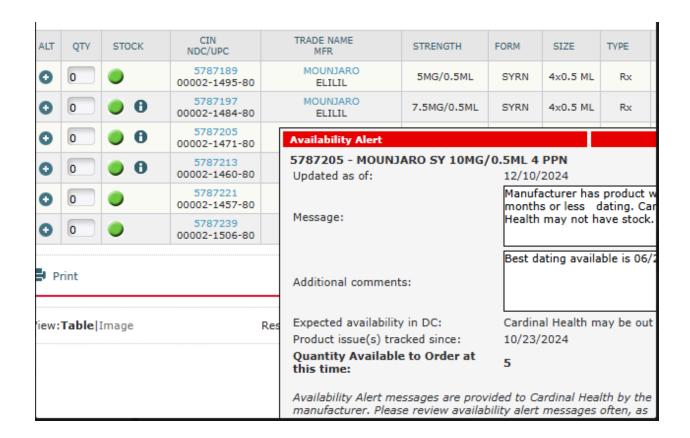
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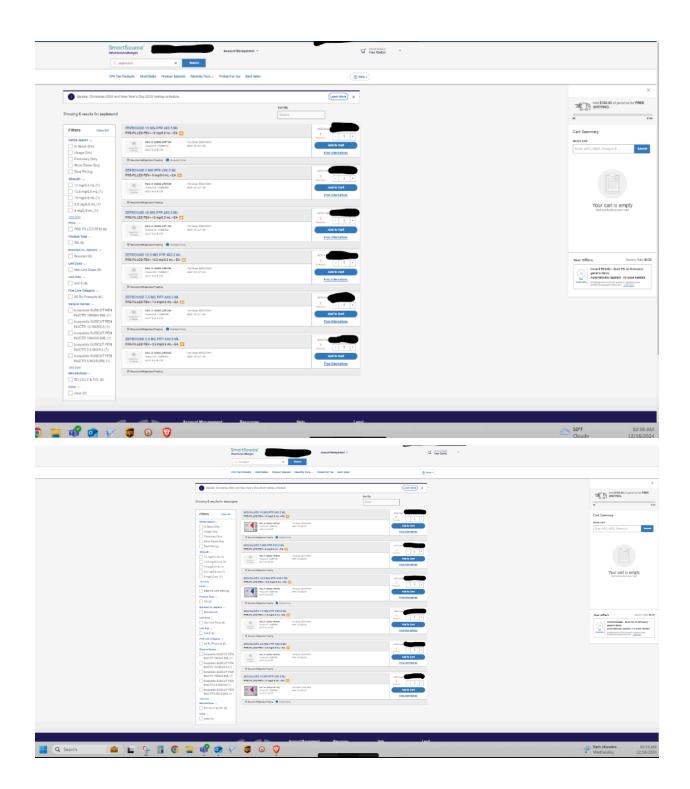
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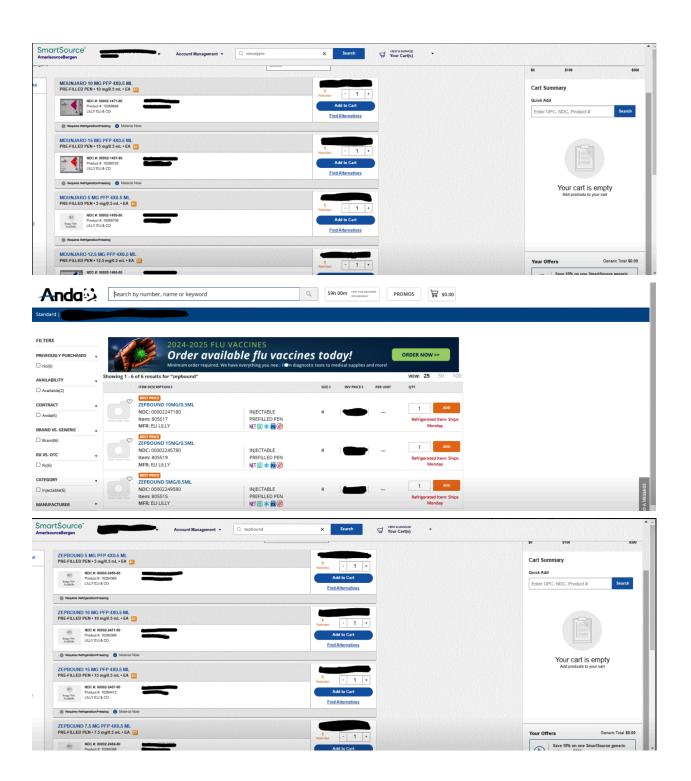
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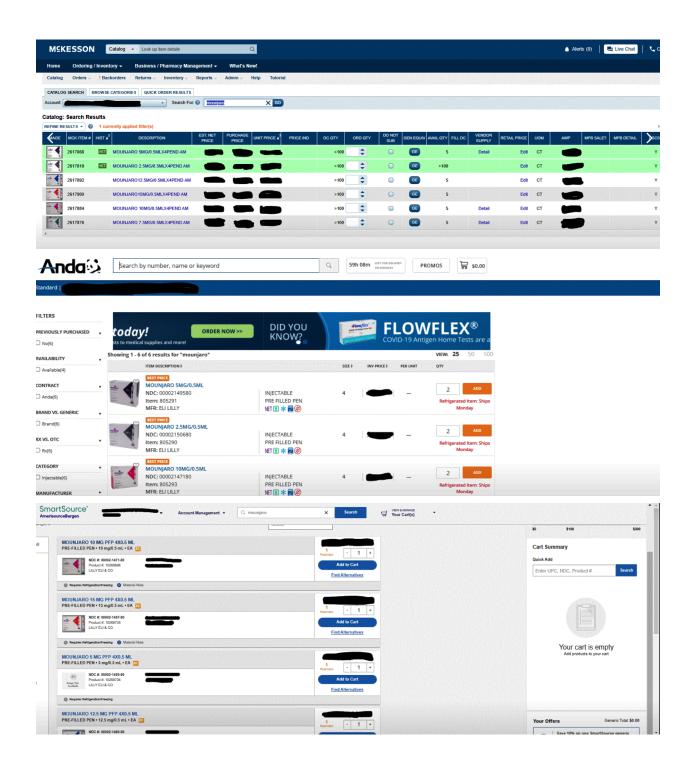
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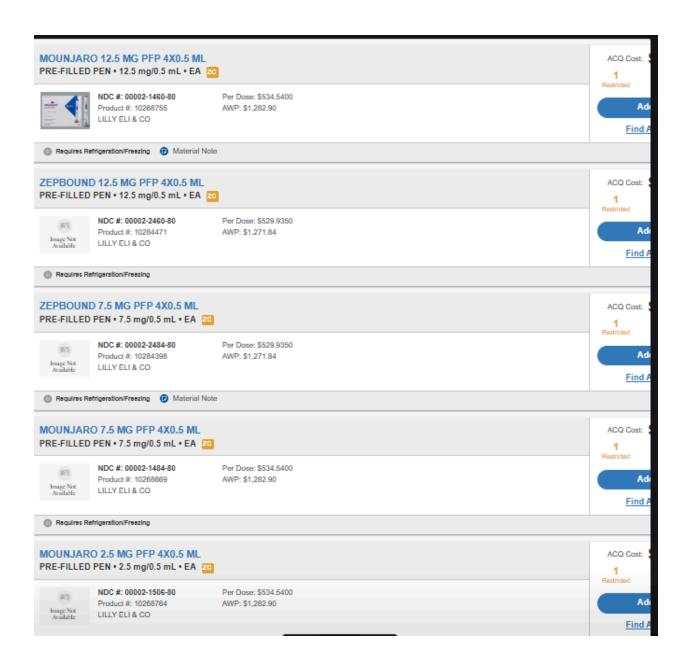


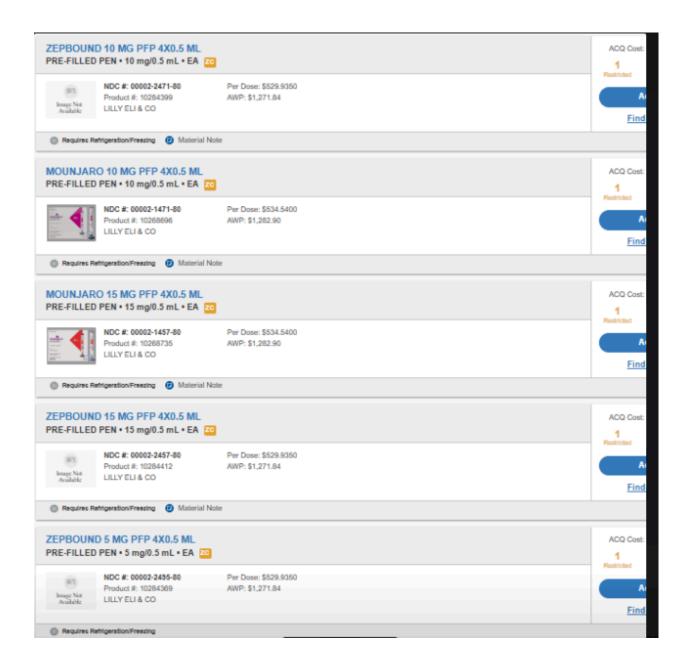
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0	0		5884929 00002-2495-80		ZEPBOUND ELILIL	5MG/0.5ML	SYRN	4x0.5 ML	Rx	
0	0		5884937 00002-2484-80		ZEPBOUND ELILIL	7.5MG/0.5ML	SYRN	4x0.5 ML	Rx	
0	0		5884945 00002-2471-80		ZEPBOUND ELILIL	10MG/0.5ML	SYRN	4x0.5 ML	Rx	
0	0		5884952 00002-2460-80		ZEPBOUND ELILIL	12.5MG/0.5ML	SYRN	4x0.5 ML	Rx	
0	0	<b>0</b>	5884960 00002-2457-80		Availability Alert					
Print  'iew: <b>Table</b>  Image Res			5884960 - ZEPBOUND SY 15MG/0 Updated as of:  Message:		12/10/ Manufa Cardina receivi Until si	12/10/2024  Manufacturer backorder - Cardinal Health may still be receiving periodic shipments Until supply is sufficient to r customer demand. Cardinal				
				Additional comments:						
			Expected availability in DC: Product issue(s) tracked since: Quantity Available to Order at this time:		Date not provided by manuf 11/22/2024 5					
Customer Service: 1-800-926-3161   Hel			Availability Alert messages are provided to Cardinal Health by the manufacturer. Please review availability alert messages often, as information is updated frequently.							

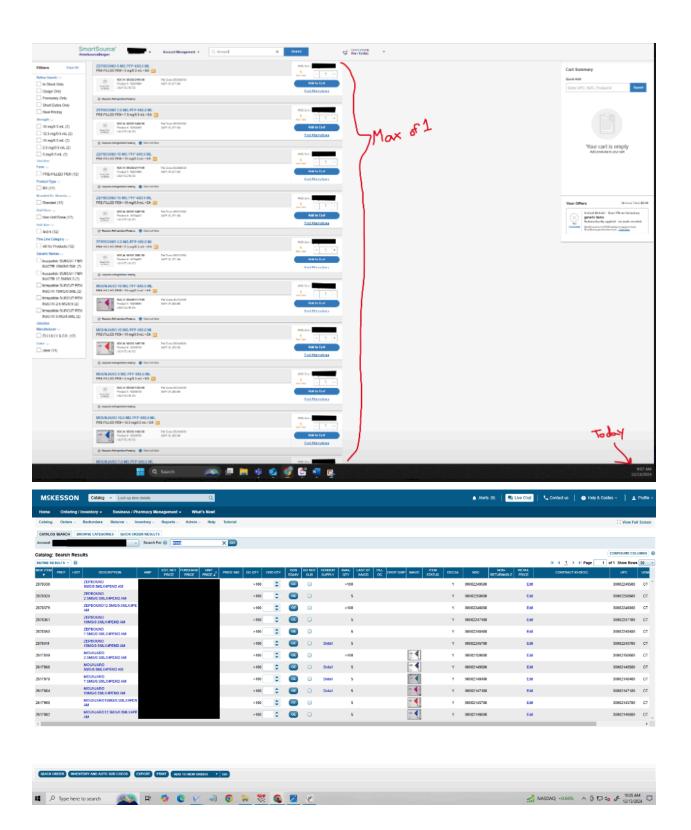


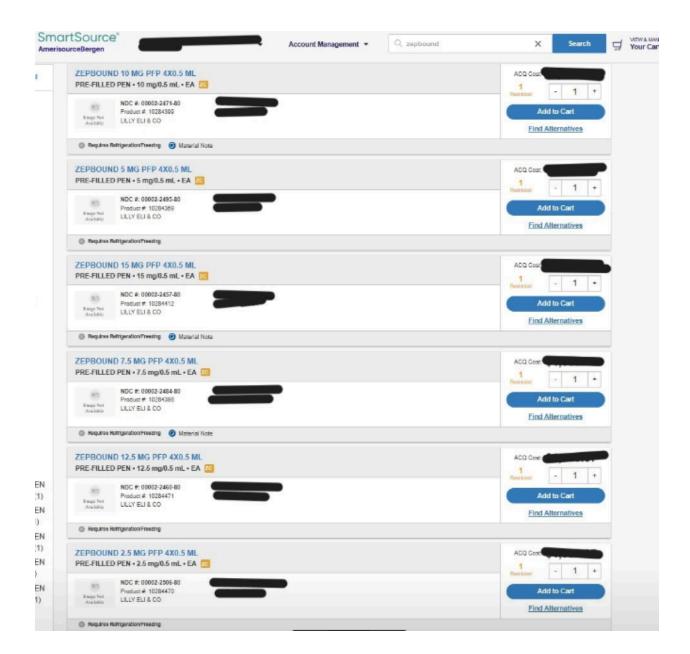


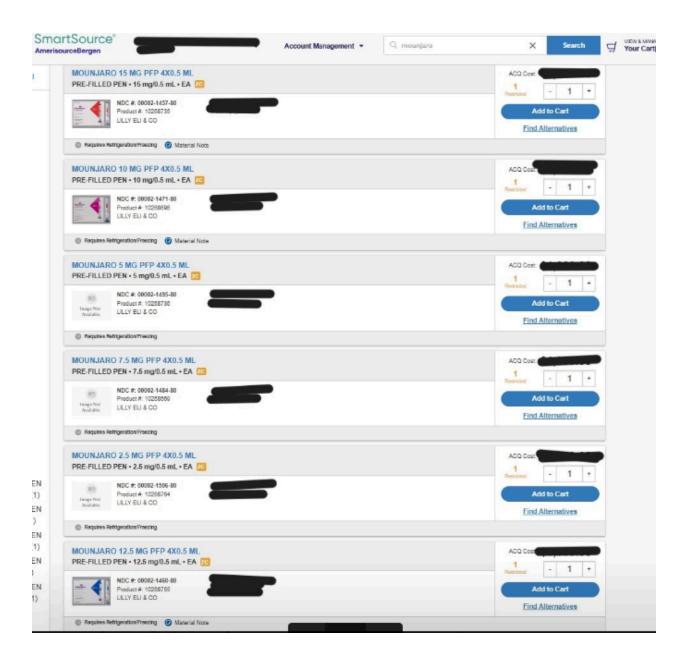


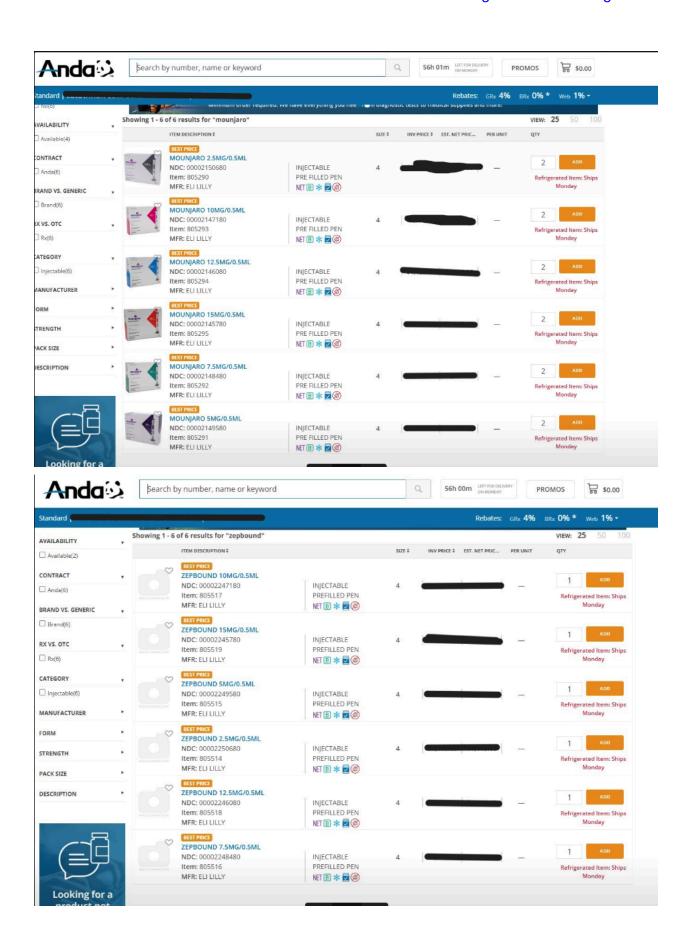


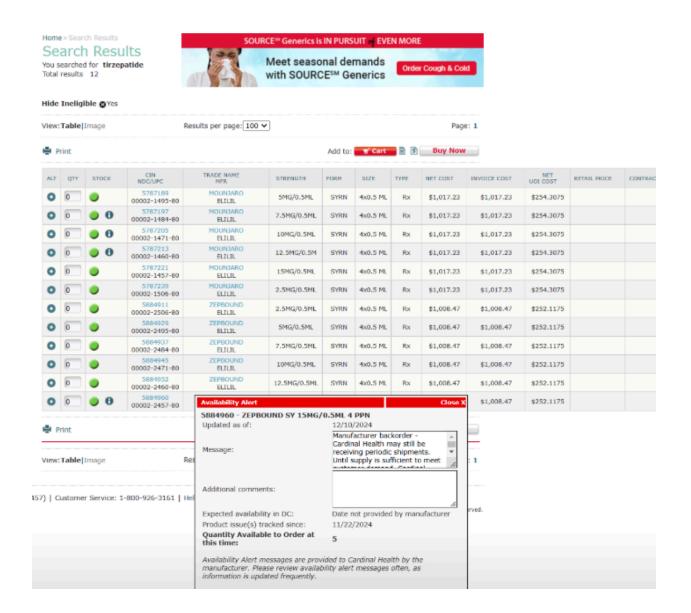


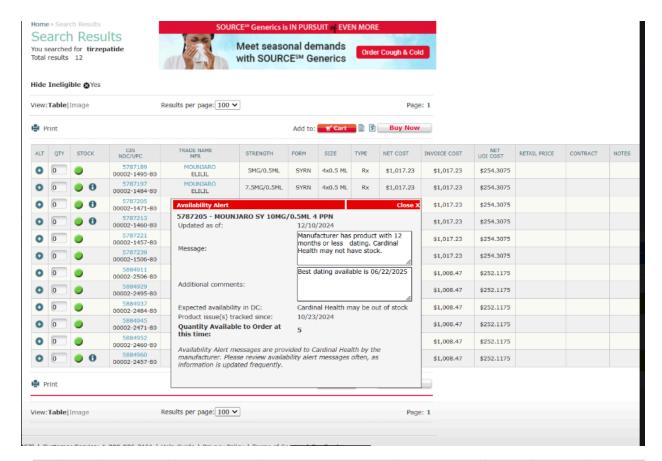






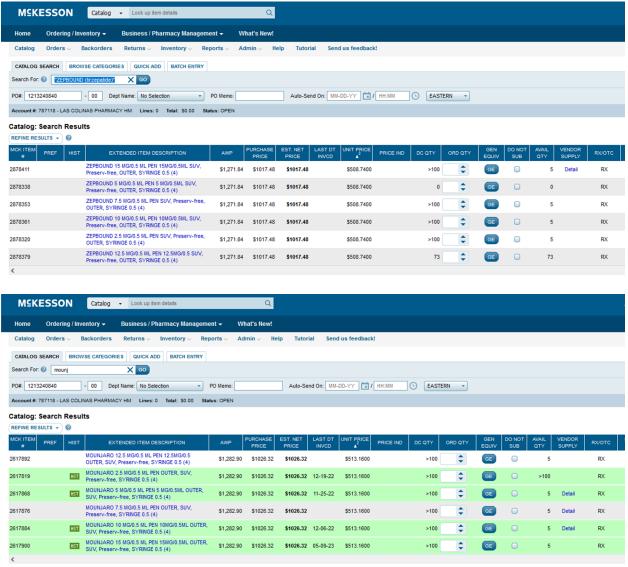


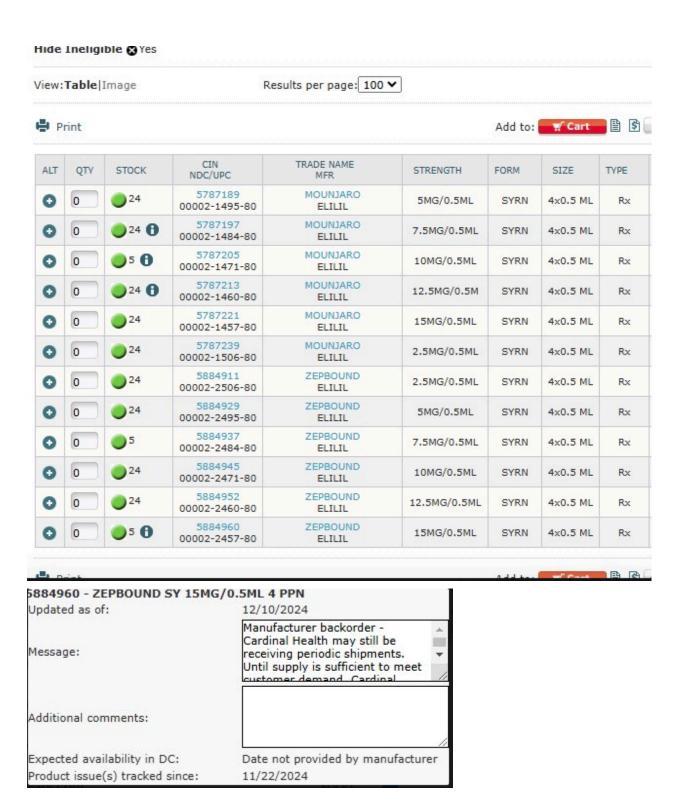


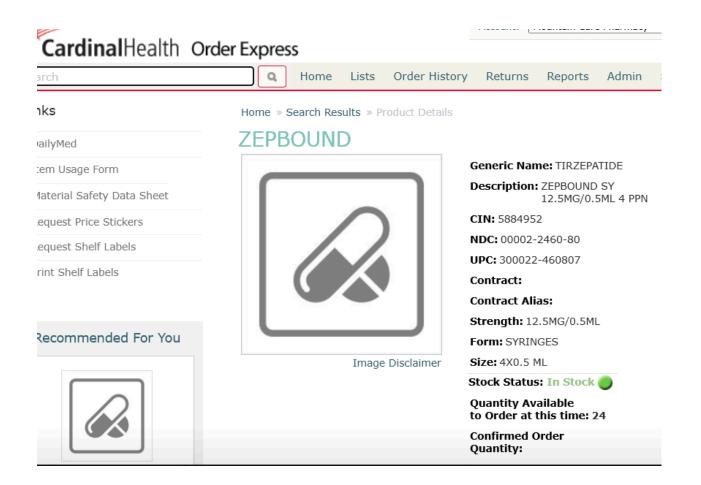


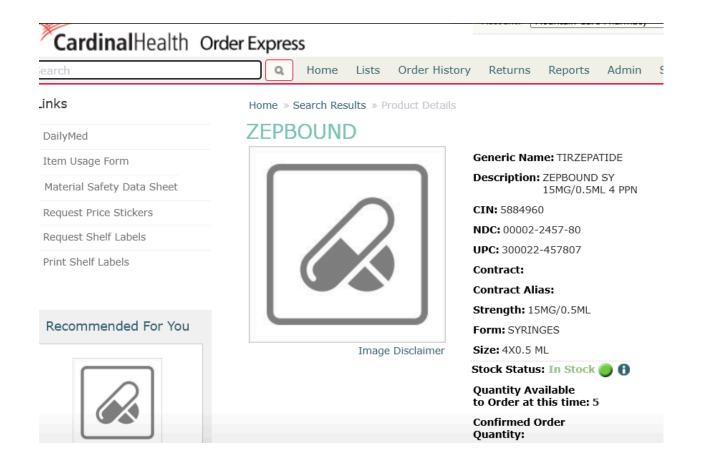
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0	0	<b>0</b>	5787197 00002-1484-80	MOUNJARO ELILIL	7.5MG/0.5ML	SYRN	4x0.5 ML	Rx
0	0	<b>0</b>	5787205 00002-1471-80	MOUNJARO ELILIL	10MG/0.5ML	SYRN	4x0.5 ML	Rx
0	0	<b>0 0</b>	5787213 00002-1460-80	MOUNJARO ELILIL	12.5MG/0.5M	SYRN	4x0.5 ML	Rx
0	0		5787221 00002-1457-80	MOUNJARO ELILIL	15MG/0.5ML	SYRN	4x0.5 ML	Rx
0	0	•	5787239 00002-1506-80	MOUNJARO ELILIL	2.5MG/0.5ML	SYRN	4x0.5 ML	Rx

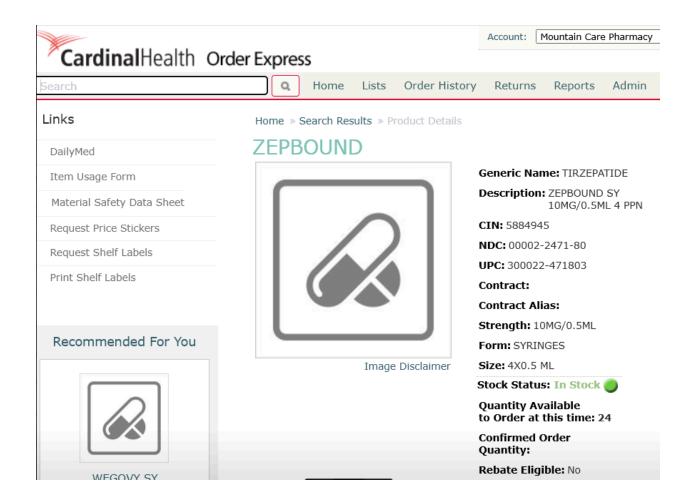


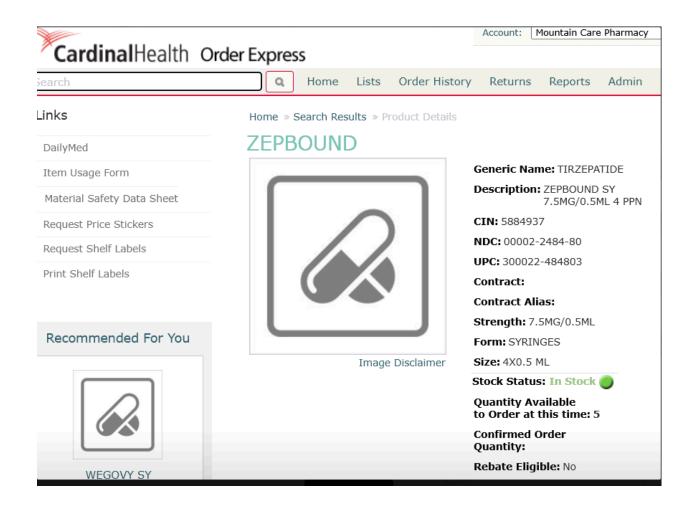


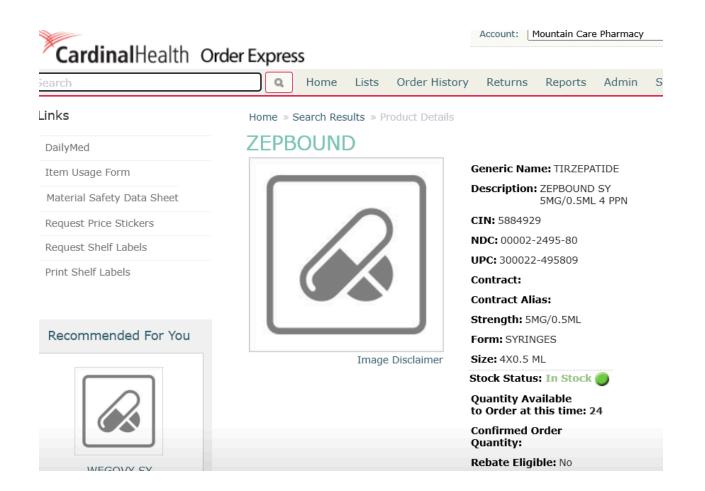


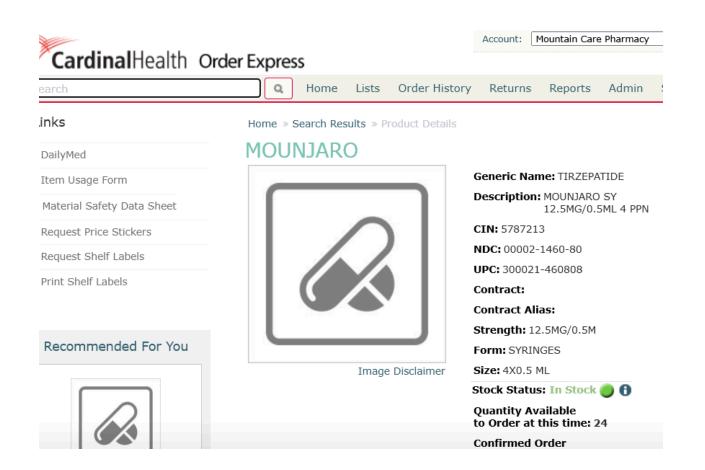


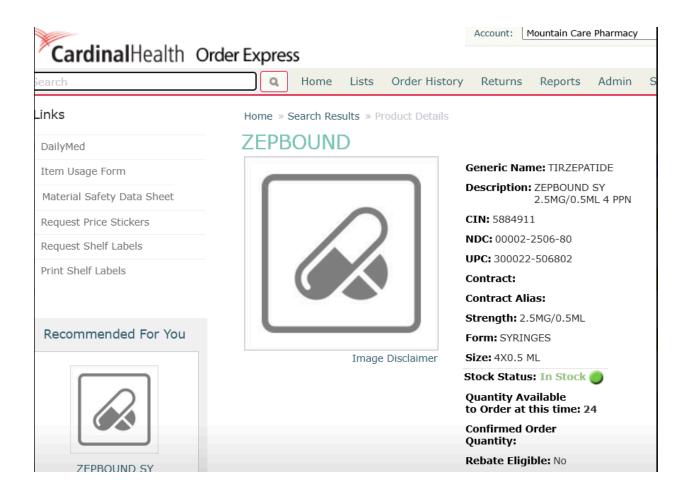


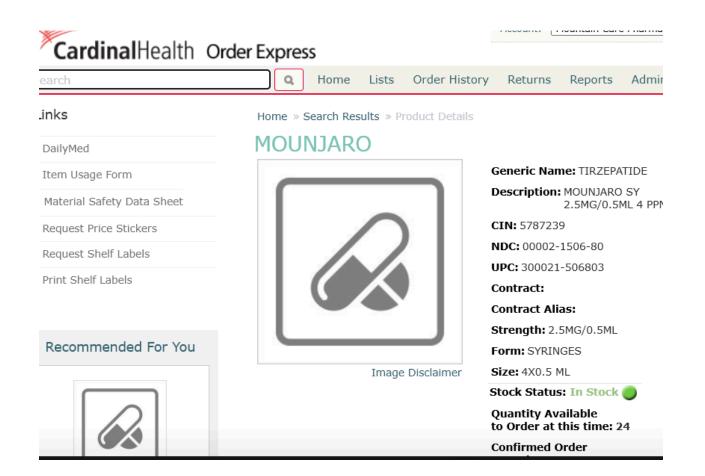












Home » Search Results » Product Details

### **MOUNJARO**



Image Disclaimer

Generic Name: TIRZEPATIDE

Description: MOUNJARO SY

10MG/0.5ML 4 PPN

CIN: 5787205

NDC: 00002-1471-80

UPC: 300021-471804

Contract:

Contract Alias:

Strength: 10MG/0.5ML

Form: SYRINGES

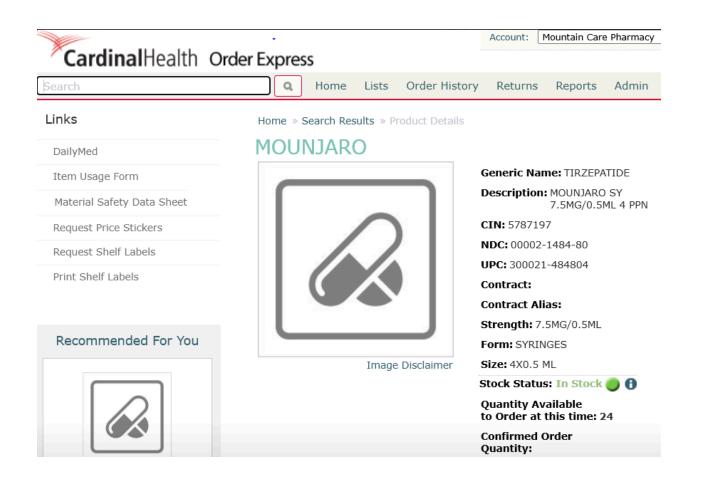
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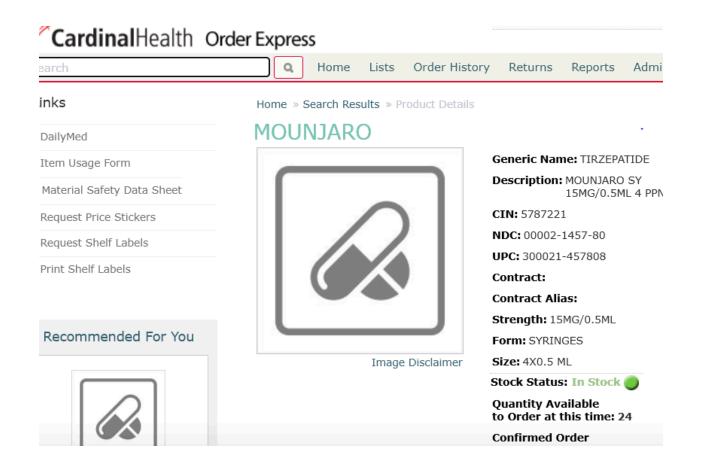
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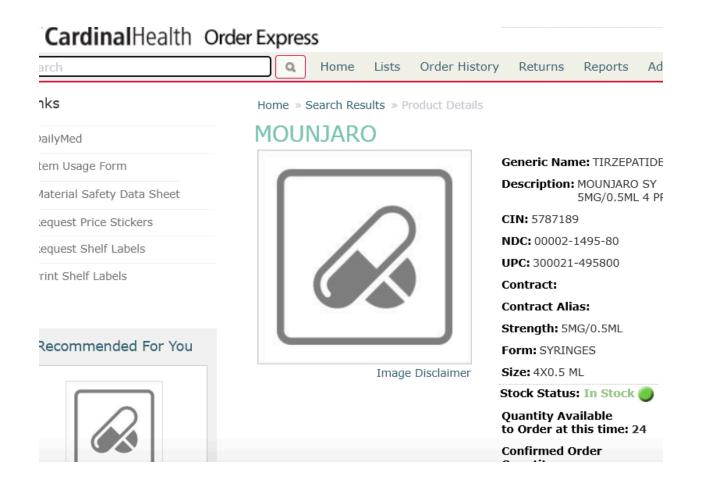
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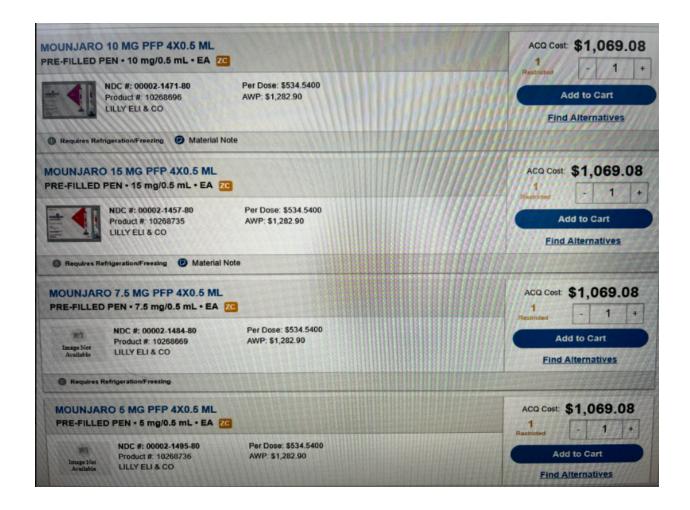
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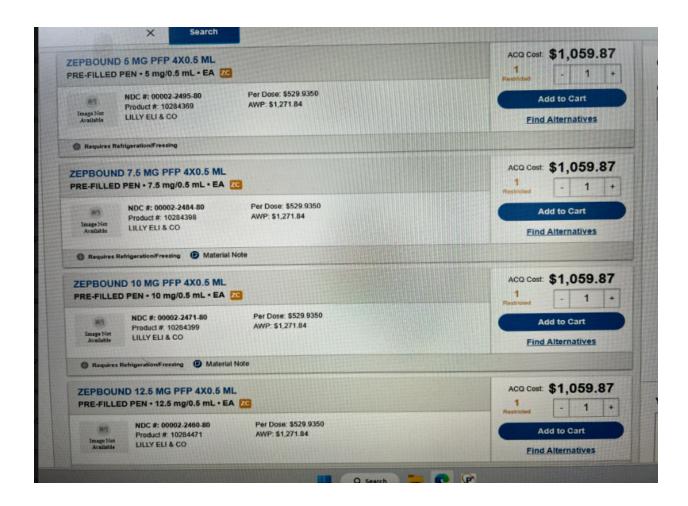
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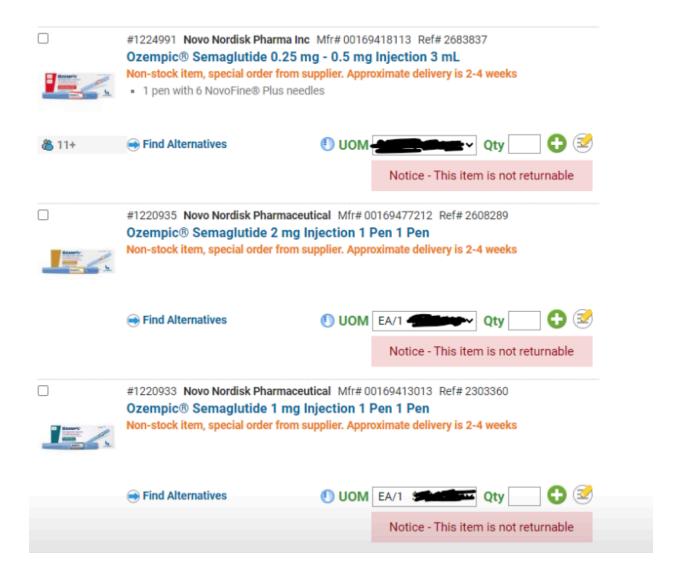






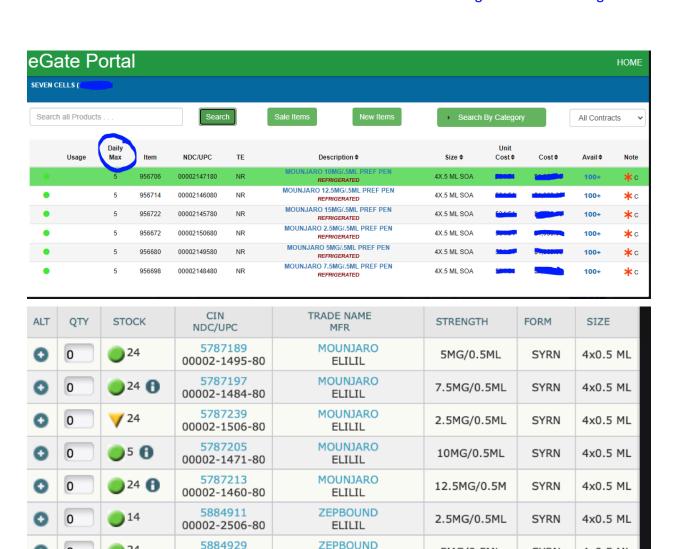






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24	5884911 00002-2506-80	ZEPBOUND ELILIL	2.5MG/0.5ML	SYRN	4x0.5 ML	Rx
<b>)</b> 5	5884937 00002-2484-80	ZEPBOUND ELILIL	7.5MG/0.5ML	SYRN	4x0.5 ML	Rx
24	5884945 00002-2471-80	ZEPBOUND ELILIL	10MG/0.5ML	SYRN	4x0.5 ML	Rx
24	5884952 00002-2460-80	ZEPBOUND ELILIL	12.5MG/0.5ML	SYRN	4x0.5 ML	Rx
<b>)</b> 5 <b>⊕</b>	5884960 00002-2457-80	ZEPBOUND ELILIL	15MG/0.5ML	SYRN	4x0.5 ML	Rx
<b>/</b> 24	5787189 00002-1495-80	MOUNJARO ELILIL	5MG/0.5ML	SYRN	4x0.5 ML	Rx
<b>)</b> 24 <b>()</b>	5787197 00002-1484-80	MOUNJARO ELILIL	7.5MG/0.5ML	SYRN	4x0.5 ML	Rx
<b>)</b> 5 <b>()</b>	5787205 00002-1471-80	MOUNJARO ELILIL	10MG/0.5ML	SYRN	4x0.5 ML	Rx
<b>V</b> 24	5787239 00002-1506-80	MOUNJARO ELILIL	2.5MG/0.5ML	SYRN	4x0.5 ML	Rx
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ZEPBOUND ZEPBOUND

**ELILIL** 

**ZEPBOUND** 

ELILIL

**ZEPBOUND** 

**ELILIL** 

**ZEPBOUND** 

**ELILIL** 

**MOUNJARO** 

**ELILIL** 

5MG/0.5ML

7.5MG/0.5ML

10MG/0.5ML

12.5MG/0.5ML

15MG/0.5ML

15MG/0.5ML

**SYRN** 

**SYRN** 

SYRN

**SYRN** 

**SYRN** 

**SYRN** 

4x0.5 ML

4x0.5 ML

4x0.5 ML

4x0.5 ML

4x0.5 ML

4x0.5 ML

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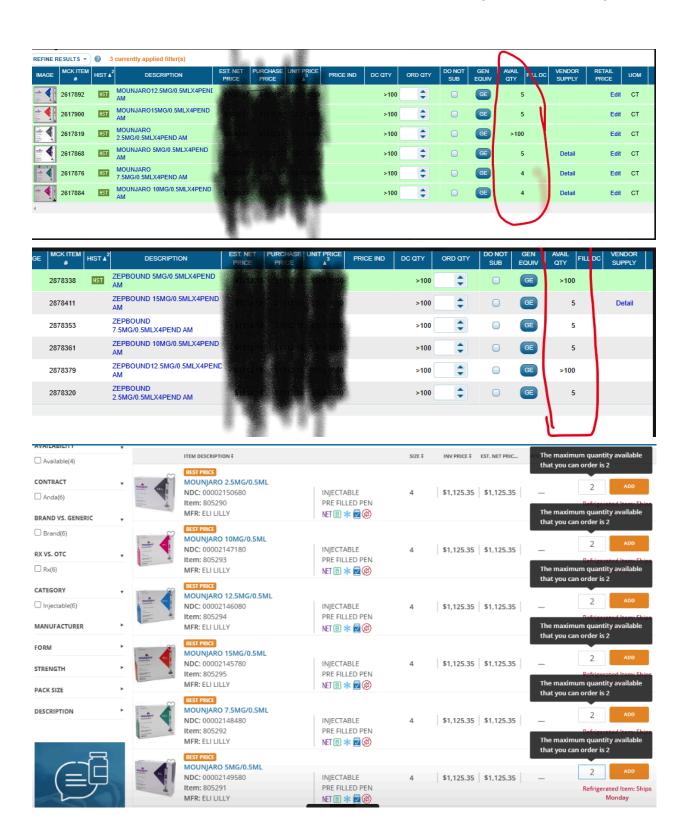
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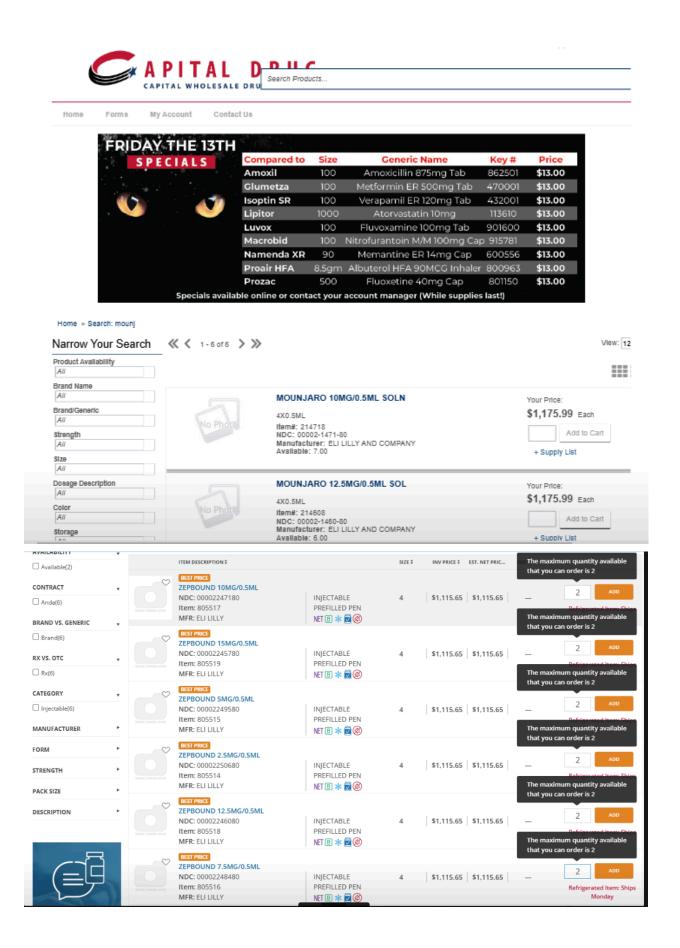
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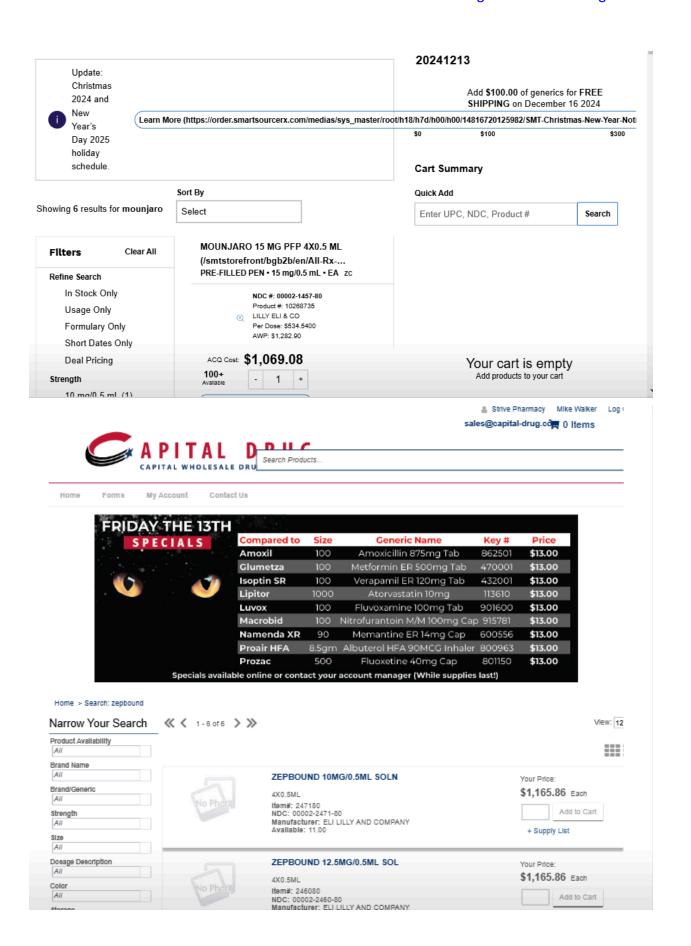
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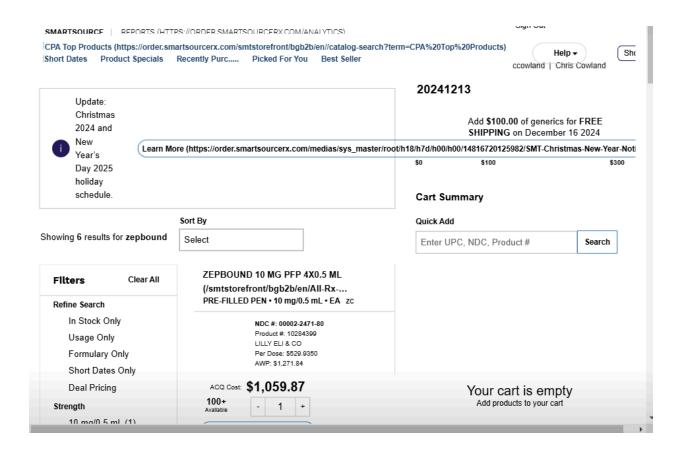
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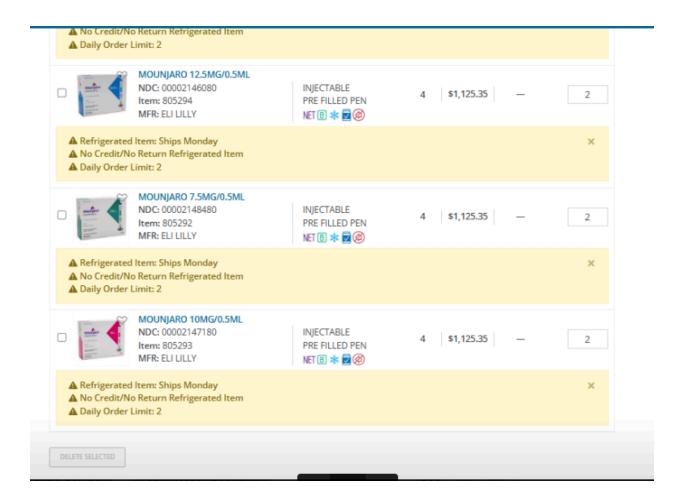
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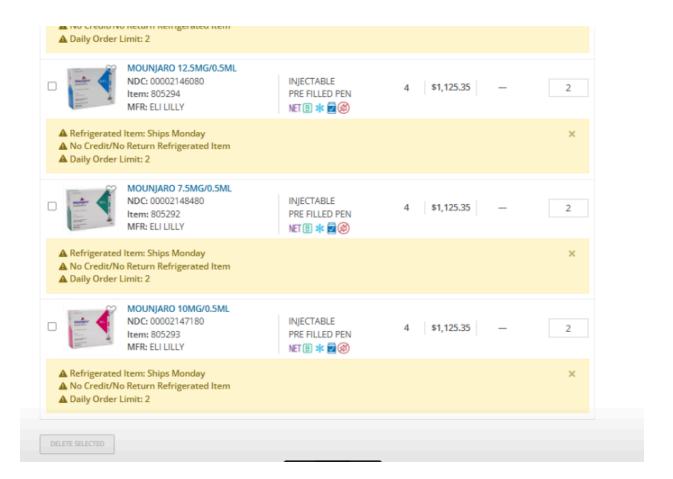


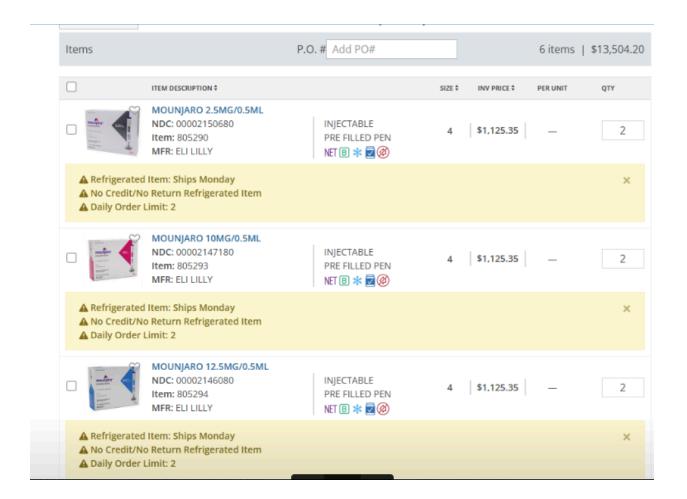


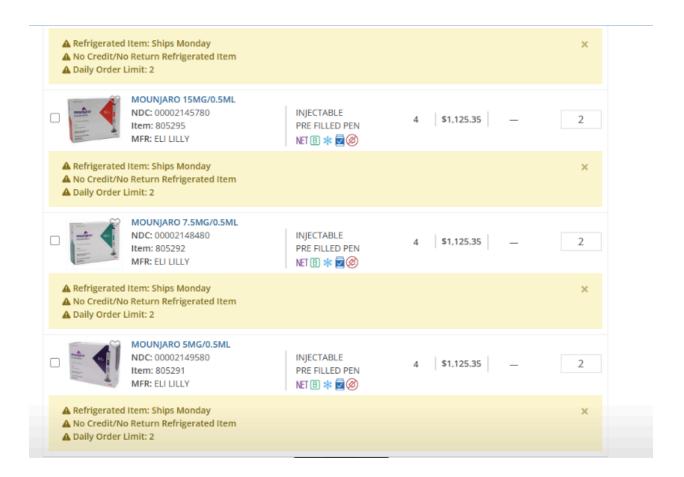


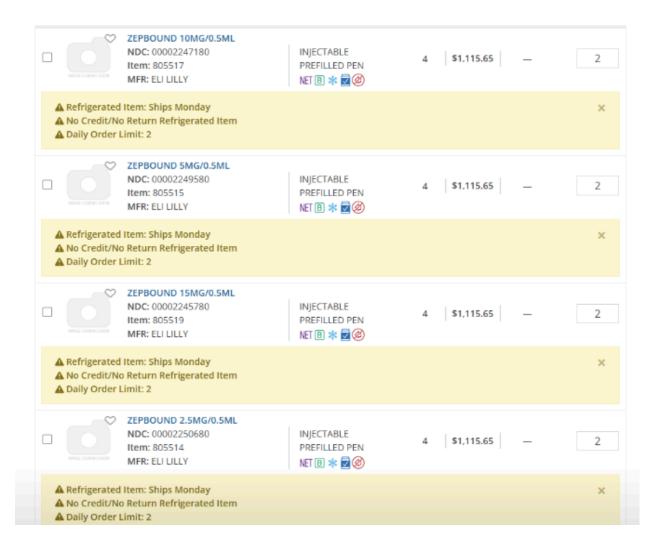


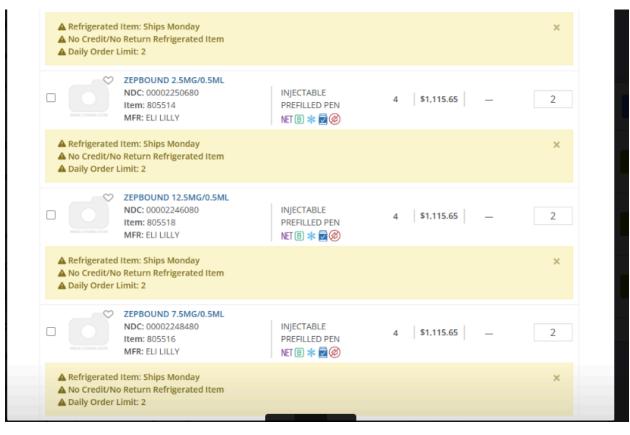


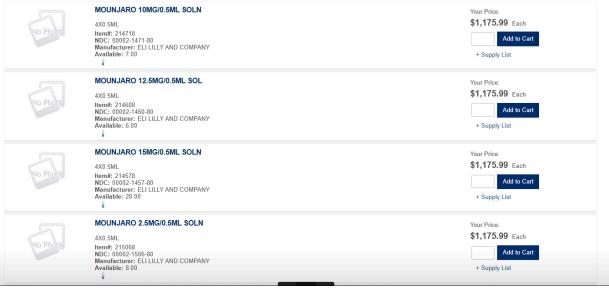


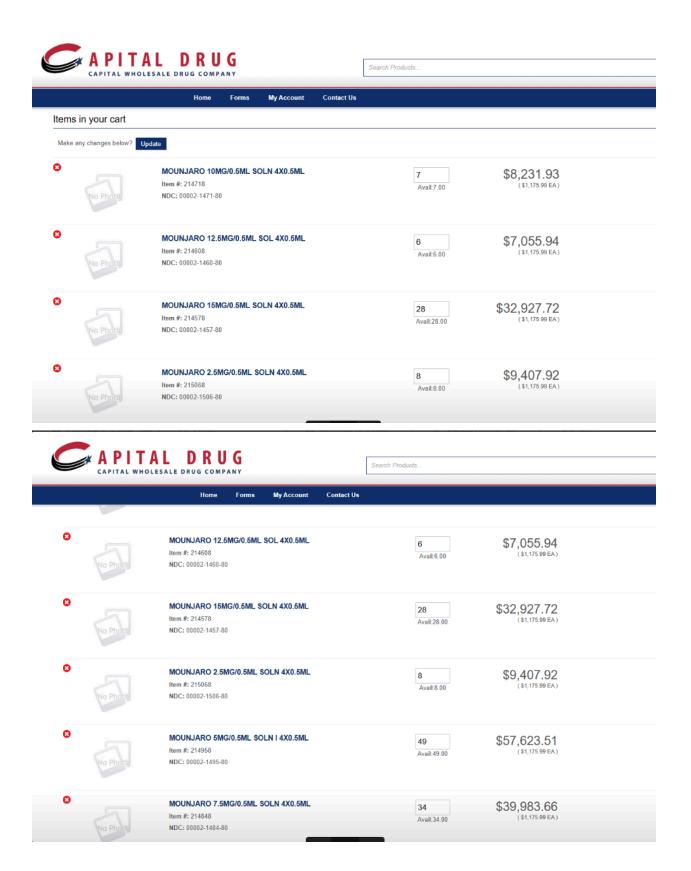


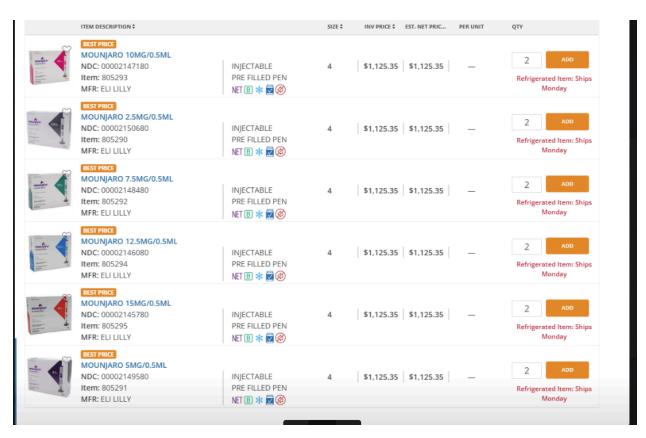


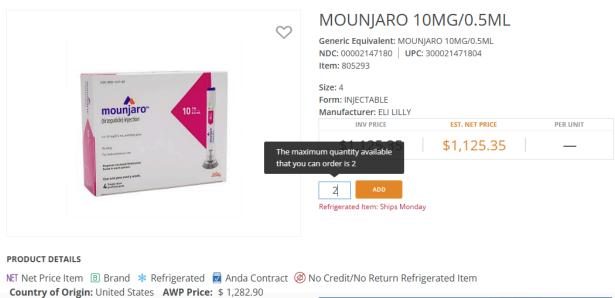


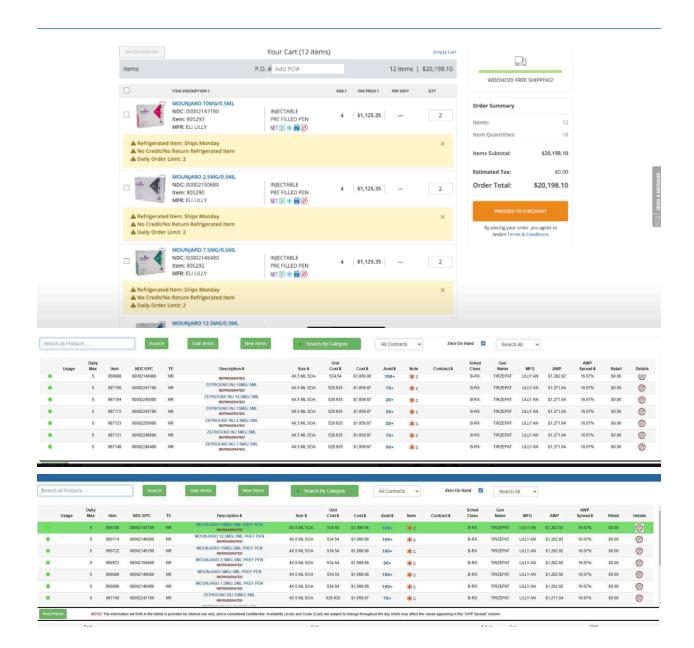


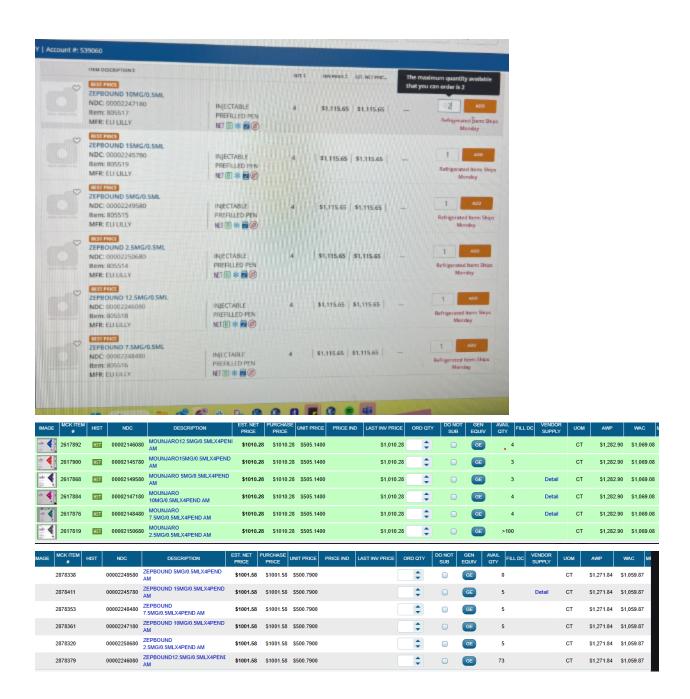






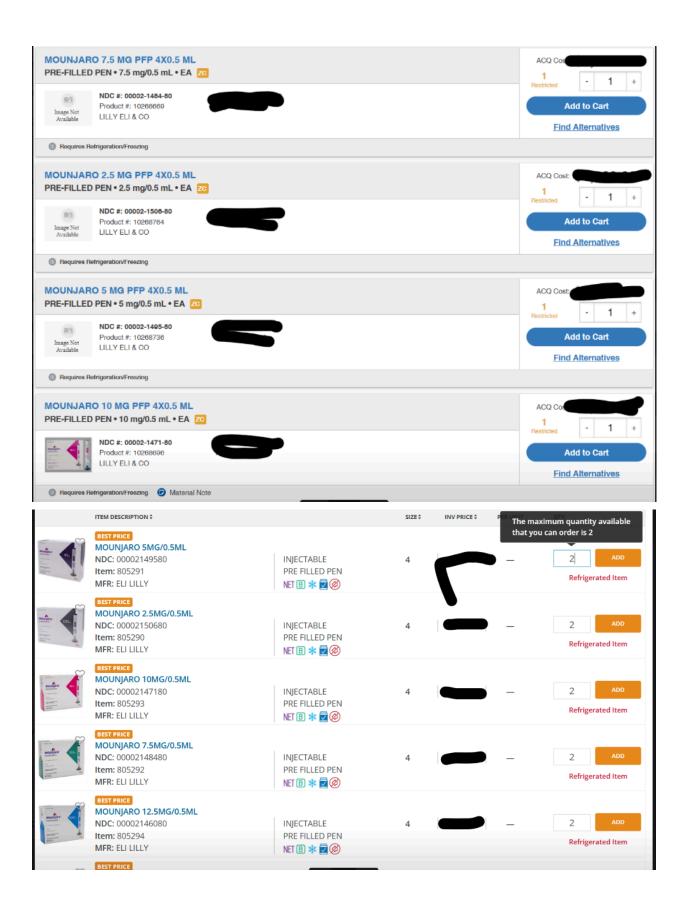


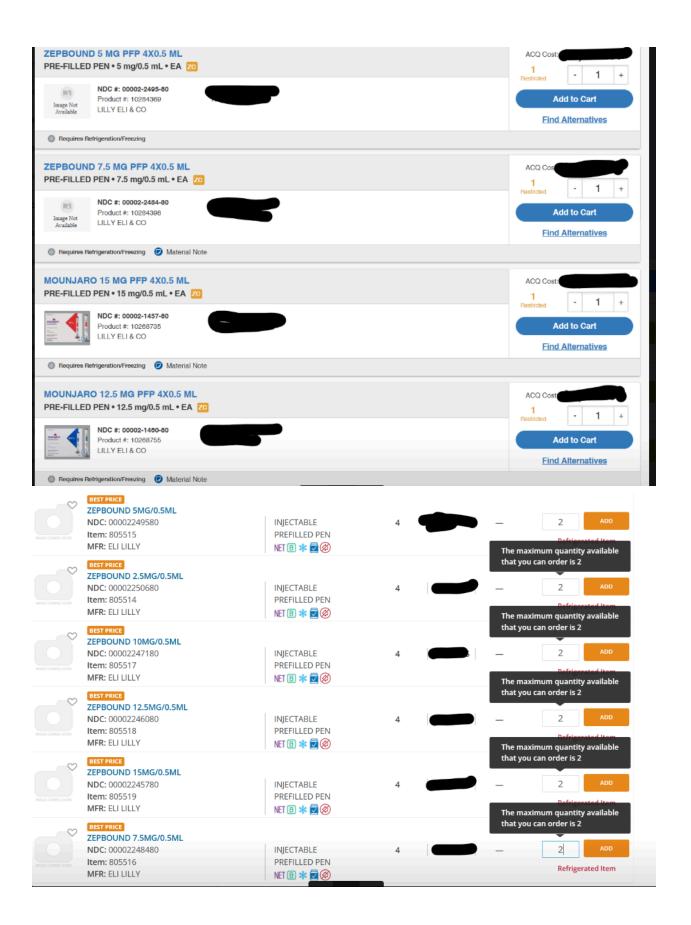


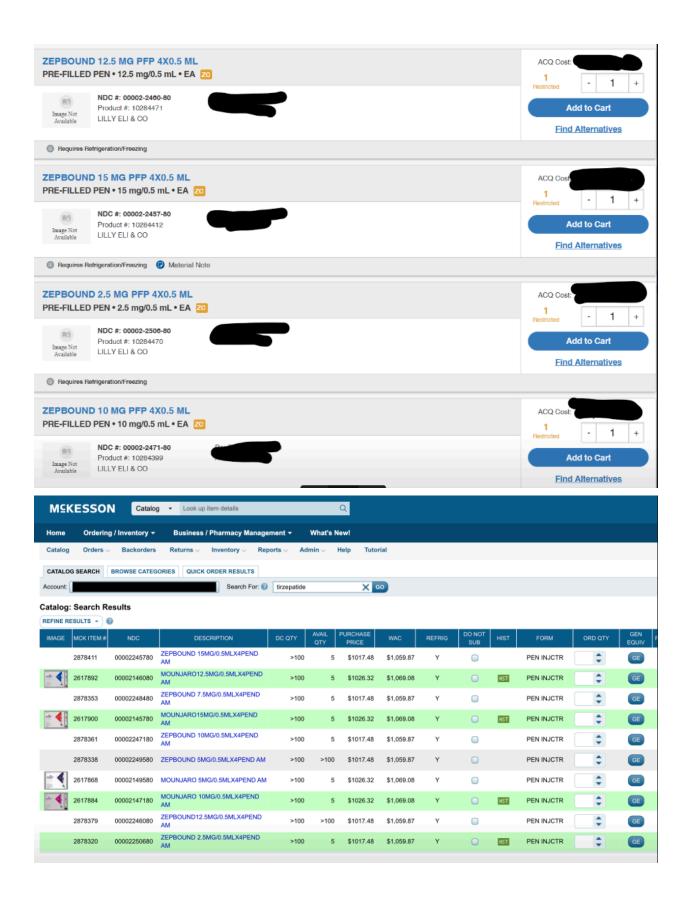


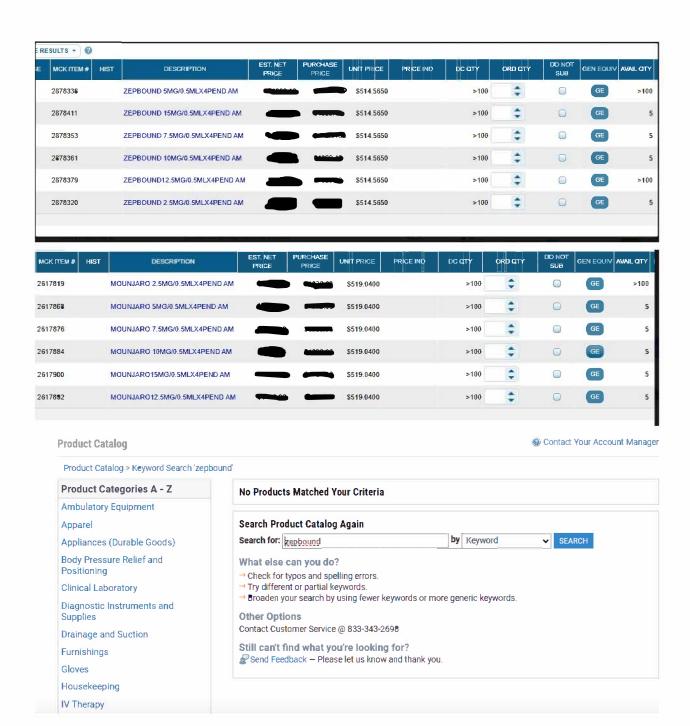


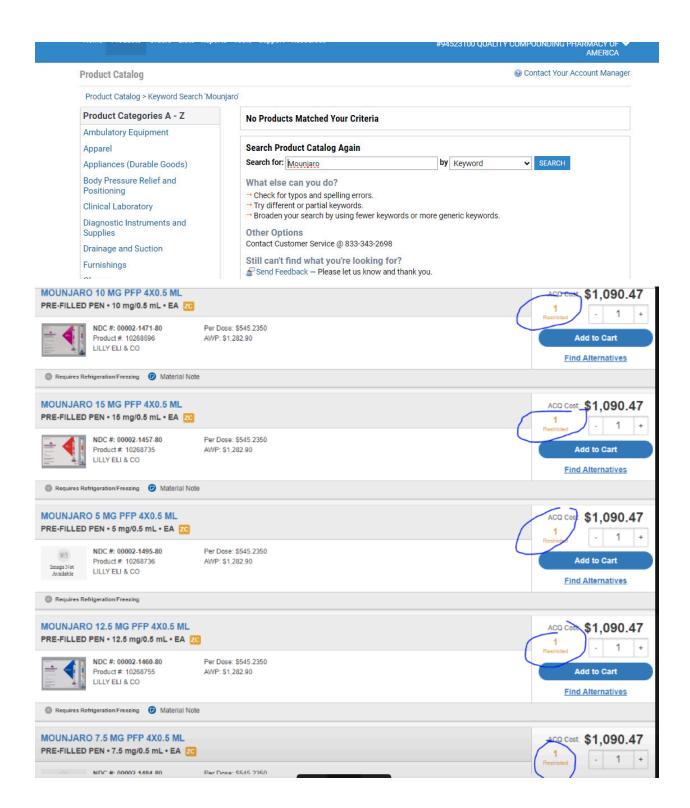


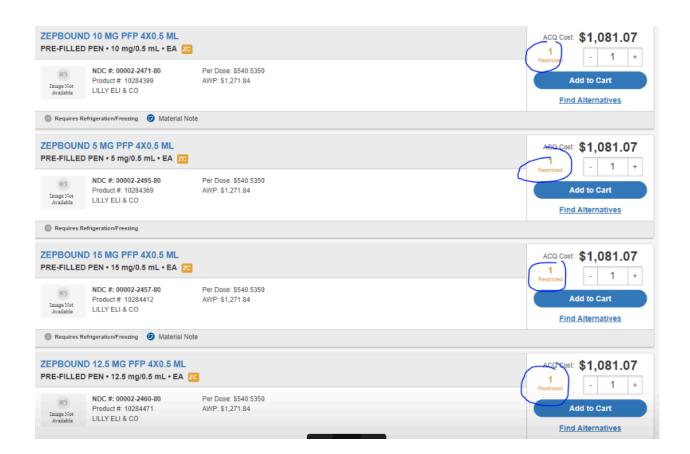


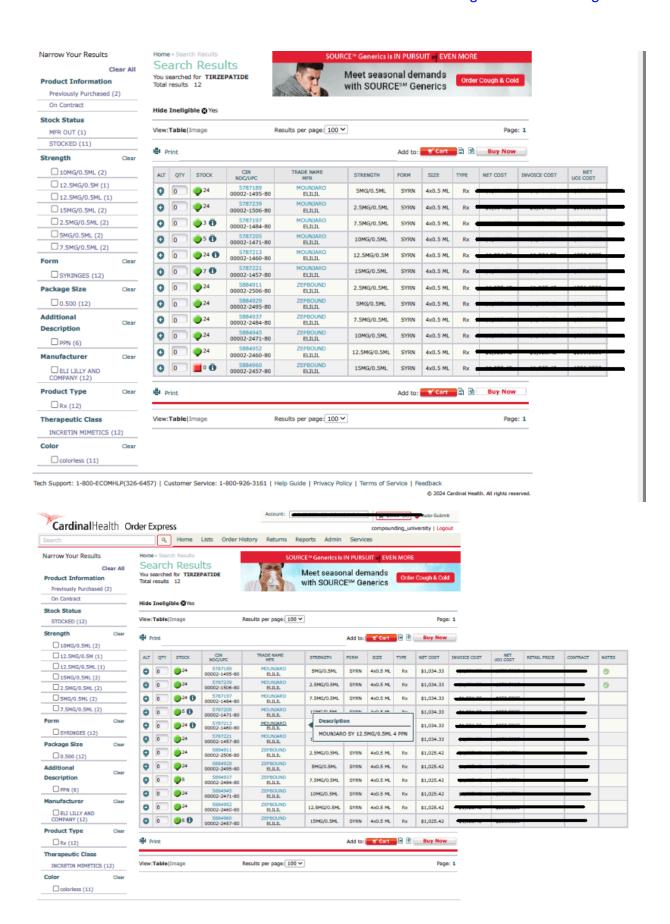


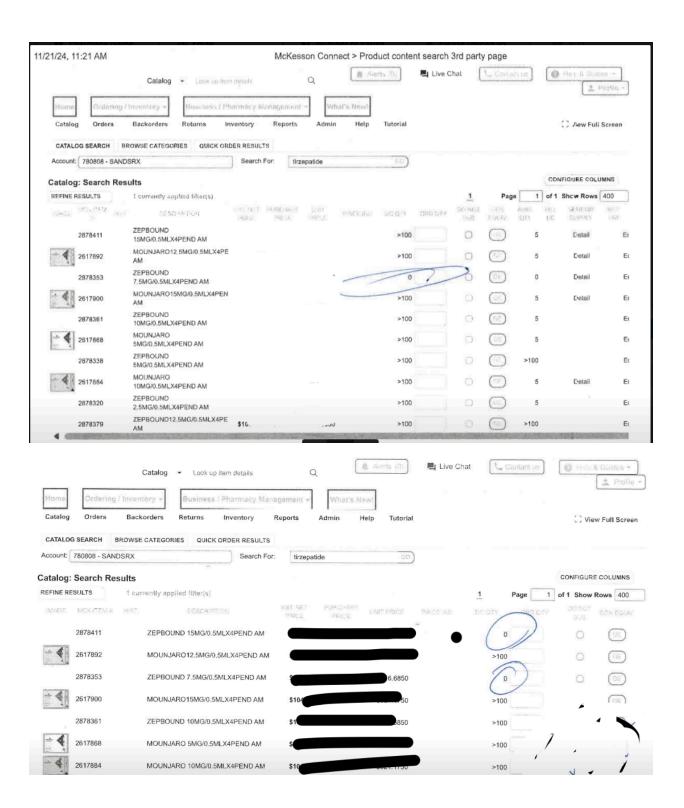












## Exhibit 40

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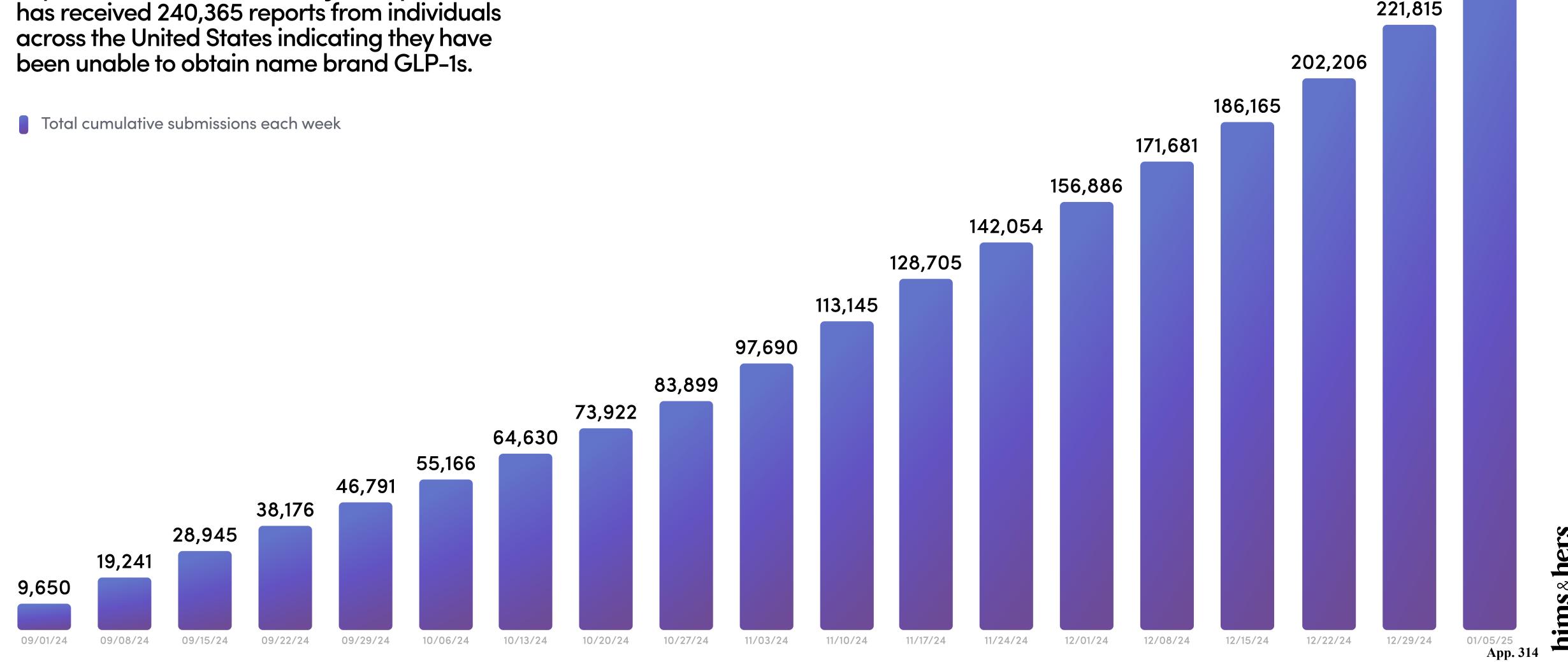


# hims a hers

240,365

## Over 240,000 people have reported an inability to access name brand GLP-1s

Hims & Hers initiated data collection on September 1, 2024, and as of January 11, 2025 has received 240,365 reports from individuals across the United States indicating they have

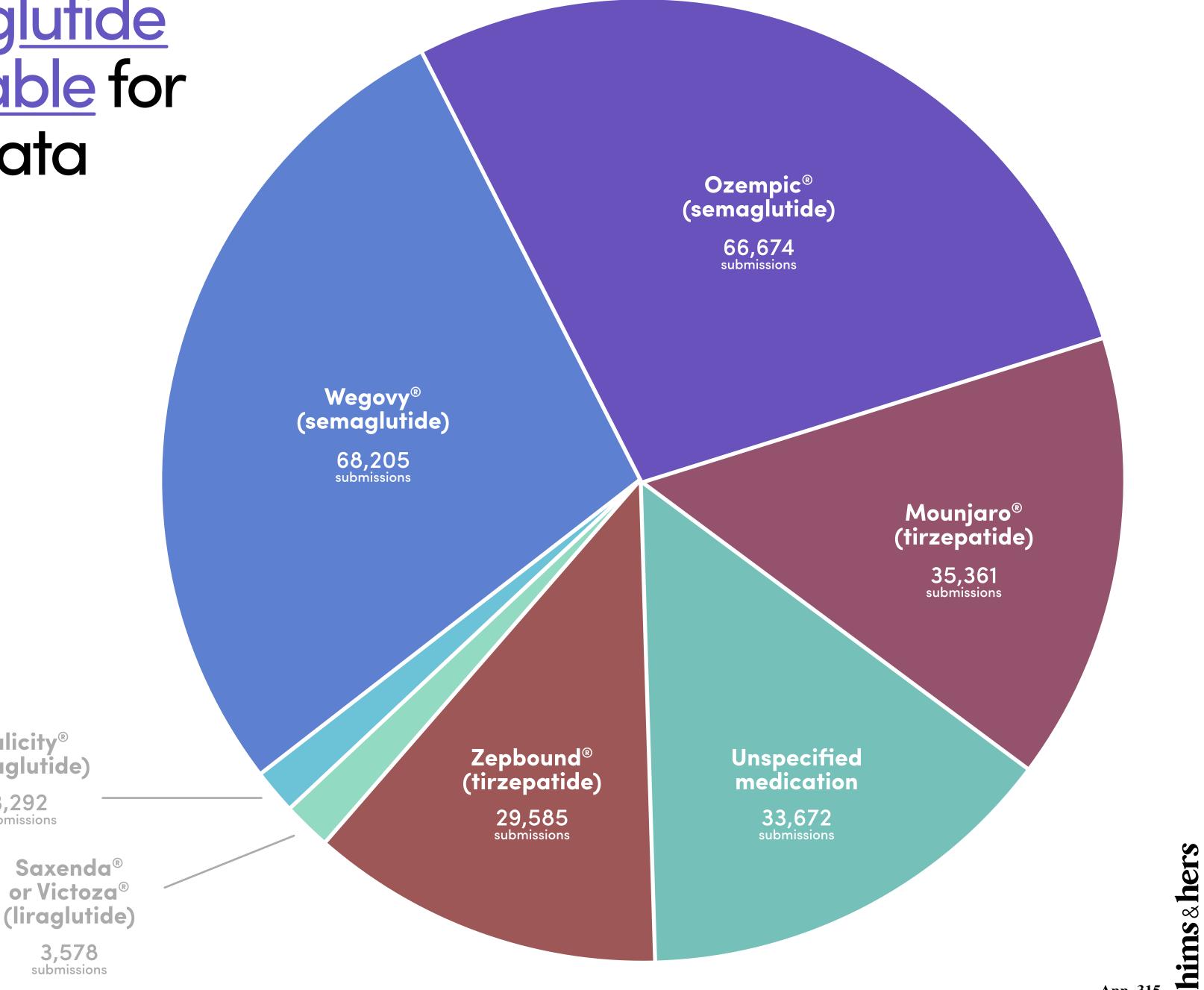


Tirzepatide and semaglutide remain widely unavailable for consumers reporting data through our platform

**Trulicity**®

(dulaglutide)

submissions



## Our affiliated pharmacies continue to <u>struggle to source</u> branded GLP-1s across our leading wholesale partners

Supplier data collected 01/13/2025



